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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/502,664 | 02/11/2000 | Ronald D. Vale | REGEN1500-1 | 5502 |

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[REDACTED] EXAMINER

ROBINSON, HOPE A

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1653

DATE MAILED: 11/26/2001

11

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/502,664 | VALE ET AL. |
| | Examiner Hope A. Robinson | Art Unit 1653 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 August 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-103 is/are pending in the application.
 - 4a) Of the above claim(s) 13-103 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) 4-7 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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DETAILED ACTION

1. The communication mailed November 6, 2001 in Paper No. 9 has been vacated in favor of the following office action.
2. Applicant's election with traverse of Group I (claims 1-12 with agarose) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that Groups I, IV, V, VII and VIII not be restricted from each other and Groups II and III. Applicant argues that the elected Group I and Groups IV, V, VII and VIII all are directed to methods of isolating a polypeptide which is modified to contain a FlAsH target sequence motif, at least by binding the polypeptide to a FlAsH binder compound, which is immobilized to a solid support. This argument is not convincing because as stated in Paper No. 6, Groups I, IV, V, VII and VIII are all different methods of isolating a polypeptide of interest and that the steps involved and/or structure of the polypeptides in the five methods all differ from each other. In addition, Groups II and III differ from each other in that they are different DNA constructs that differ in structure at their 5' and 3' ends. It is noted that applicant agrees that the polypeptides differ with regard to whether they have been modified. Modification of the protein sequence results in a physically and structurally different product, hence a different protein. Applicant further contends that while the claims of Groups I, IV, V, VII and VIII are directed to subject matter that is independent and patentably distinct, it is submitted that the position of the FlAsH target sequence with respect to a terminus of a

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polypeptide to be isolated is not a sufficient basis for dividing the groups. Applicant offers the same argument for the election of species, as it is argued that while the species as set forth are independent and patentably distinct, the various solid supports share a commonality of operation, function and effect with respect to the present invention. Applicant is directed to MPEP Chapter 800 where it is stated that a restriction requirement is proper if it can be shown that the invention is independent (no disclosed relationship) or distinct (disclosed relationship). Thus, the restriction requirement is proper and is final.

3. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Oath/Declaration

4. The Oath/Declaration is objected to because non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specification

5. The specification is objected to because of the following informalities:

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The specification is objected to because on page 1 the priority document number is missing.

Correction is required.

Claim Objection

6. Claims 4-7 are objected to because the claims refer to a protein sequence and no sequence identifier is provided.

Compliance with the sequence rules is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 is indefinite for the recitation of a method comprising contacting “ a modified FlAsH and modified polypeptide” without reciting how the FlAsH has been modified or how the protein is to be modified (i.e., where in the protein structure will the FlAsH target sequence motif

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be inserted). The claim is also indefinite with regard to the “solid support” as the claim does not recite the type of “solid support”.

Claims 4-7 are indefinite as they refer to a sequence and no sequence identifier is provided.

Claim 8 is rejected as being indefinite because the claims contain the trademark/trade name Nylon™ and Teflon™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the preparation and, accordingly, the identification/description is indefinite.

Claims 2, 3 and 9-12 are indefinite as the claims depend from a rejected based claim.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4-7 and 9-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Tsien et al. (U.S. Patent No. 6,008,378, December 28, 1999).

Tsien teach biarsenical molecules and target sequence (FlAsH) see Figure 3. Tsien teaches that the biarsenical molecule preferably is capable of traversing a biological membrane, and includes a detectable group, for example, fluorescent group, luminescent group, phosphorescent group, spin label, photosensitizer, photocleavable moiety, chelating center, heavy atom, radioactive isotope, isotope detectable by nuclear magnetic resonance, paramagnetic atom and combinations thereof (see specification page 4 where the modified FlAsH is defined and claim 1 of the present application). Tsien also teach examples of these groups in Figures 6, 8 and 9 which demonstrates a modified FlAsH (see claim 1). Tsien further teaches that the biarsenical molecule is bonded to a dithiol such as EDT (see claims 9 and 10) and may be coupled to a solid phase (see claim 1). In addition, Tsien teaches that the target sequence may be modified by the addition of the motif Cys-Cys-X-Y-Cys-Cys, wherein X and Y are amino acids (the same or different amino acids as in claims 4-7 of the application). The reference teaches that cysteines are positioned for encouraging arsenic interaction across helical turns. Finally, Tsien teaches a polypeptide in solution obtained from cells (from a eukaryote or prokaryote) and that the polypeptide is isolated

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with the use of FlAsH (see abstract, columns 1-8, claims 10-12 and Example 2 of the reference).

Thus, the teachings of the reference anticipates the present claims.

9. Claims 1, 4-7 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffin et al. (Science, vol. 281, pages 269-272, July 10, 1998).

Griffin teach the compound known as FlAsH and that it specifically interacts with proteins tagged with a Cys-Cys-X-X-Cys-Cys containing helix (see claim 1, 4-7). Griffin also teach that the dithiols EDT is used called FLASH-EDT to facilitate purification of the protein (see claims 9-10). Griffin also teaches a method of protein isolation that involves the polypeptide in solution from a eukaryote or prokaryote (claims 11 and 12). As Griffin teaches a method of protein isolation that uses the compound FlAsH in a modified form as claimed, the reference anticipates the claimed invention (see abstract and pages 269-272 of the reference).

Conclusion

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The

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Examiner can normally be reached on Monday and Wednesday- Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS 

Patent Examiner



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER